

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

To:
 MARK G. LAPPIN
 MCDERMOTT WILL & EMERY LLP
 28 STATE STREET
 BOSTON, MA 02109

PCT

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL SEARCH REPORT AND THE WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY, OR THE DECLARATION

(PCT Rule 44.1)

Applicant's or agent's file reference 63564-104	Date of mailing (day/month/year) 06 SEP 2005
International application No. PCT/US04/27158	FOR FURTHER ACTION See paragraphs 1 and 4 below International filing date (day/month/year) 20 August 2004 (20.08.2004)
Applicant ACCURAY, INC.	

1. The applicant is hereby notified that the international search report and the written opinion of the International Searching Authority have been established and are transmitted herewith.

Filing of amendments and statement under Article 19:

The applicant is entitled, if he so wishes, to amend the claims of the international application (see Rule 46):

When? The time limit for filing such amendments is normally two months from the date of transmittal of the international search report.

Where? Directly to the International Bureau of WIPO, 34 chemin des Colombettes
1211 Geneva 20, Switzerland. Facsimile No.: +41 22 740 14 35

For more detailed instructions, see the notes on the accompanying sheet.

2. The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect and the written opinion of the International Searching Authority are transmitted herewith.

3. With regard to the protest against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:

the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.
 no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. Reminders

Shortly after the expiration of **18 months** from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in Rules 90bis.1 and 90bis.3, respectively, before the completion of the technical preparations for international publication.

The applicant may submit comments on an informal basis on the written opinion of the International Searching Authority to the International Bureau. The International Bureau will send a copy of such comments to all designated Offices unless an international preliminary examination report has been or is to be established. These comments would also be made available to the public but not before the expiration of 30 months from the priority date.

Within **19 months** from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase **until 30 months** from the priority date (in some Offices even later); otherwise, the applicant must, **within 20 months** from the priority date, perform the prescribed acts for entry into the national phase before those designated Offices.

In respect of other designated Offices, the time limit of **30 months** (or later) will apply even if no demand is filed within 19 months.

See the Annex to Form PCT/IB/301 and, for details about the applicable time limits, Office by Office, see the *PCT Applicant's Guide*, Volume II, National Chapters and the WIPO Internet site.

Name and mailing address of the ISA/ US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230	Authorized officer <i>Lion Michelle L. Egan</i> Chih-Cheng Glen Kao Telephone No. (571) 272-2800
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PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference 63564-104	FOR FURTHER ACTION see Form PCT/ISA/220 as well as, where applicable, item 5 below.	
International application No. PCT/US04/27158	International filing date (day/month/year) 20 August 2004 (20.08.2004)	(Earliest) Priority Date (day/month/year) 29 August 2003 (29.08.2003)
Applicant ACCURAY, INC		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 5 sheets.



It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the Report
 - a. With regard to the language, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
 - The international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).
 - b. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, see Box No. I.
 - c. Certain claims were found unsearchable (See Box No. II)
 - d. Unity of invention is lacking (See Box No. III)
 - e. With regard to the title,
 - the text is approved as submitted by the applicant.
 - the text has been established by this Authority to read as follows:
5. With regard to the abstract,
 - the text is approved as submitted by the applicant.
 - the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.
6. With regard to the drawings,
 - a. the figure of the drawings to be published with the abstract is Figure No. 2
 - as suggested by the applicant.
 - as selected by this Authority, because the applicant failed to suggest a figure.
 - as selected by this Authority, because this figure better characterizes the invention.
 - b. none of the figures is to be published with the abstract.

INTERNATIONAL SEARCH REPORT

International application No.

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Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:
Please See Continuation Sheet

1. As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest The additional search fees were accompanied by the applicant's protest.
 No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US04/27158

Box IV TEXT OF THE ABSTRACT (Continuation of Item 5 of the first sheet)

The technical features mentioned in the abstract do not include a reference sign between parentheses (PCT Rule 8.1(d)).

NEW ABSTRACT

An image-guided radiosurgery method and system are presented that use 2D/3D image registration to keep the radiosurgical beams properly focused onto a treatment target. A pre-treatment 3D scan of the target is generated at or near treatment planning time (CT DATA). A set of 2D DRRs are generated (DRR GENERATION A and DRR GENERATION B), based on the pre-treatment 3D scan (CT DATA). At least one 2D x-ray image of the target is generated in near real time during treatment (X-RAY IMAGE A). The DRRs are registered with the x-ray images, by computing a set of 3D transformation parameters that represent the change in target position between the 3D scan and the x-ray images (IMAGE REGISTRATION). The relative position of the radiosurgical beams and the target is continuously adjusted in near real time in accordance with the 3D transformation parameters (GEOMETRIC TRANSFORMATION). A hierarchical and iterative 2D/3D registration algorithm is used, in which the transformation parameters that are in-plane with respect to the image plane of the x-ray images are computed separately from the out-of-plane transformation parameters.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US04/27158

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : A61B 5/05;A61N 5/10
US CL : 378,4,62,63,65,205;382/132;600/427,429

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
U.S. : 378,4,62,63,65,205;382/132;600/427,429

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5,901,199 A (MURPHY et al) 04 May 1999 (04.05.1999), column 4, line 20 -- column 6, line 14, column 9, lines 18-19, and figures 1 and 3.	1-3, 9, 10, 22, 85, and 87-90
Y		----- 8
Y	US 2004/0092815 A1 (SCHWEIKARD et al) 13 May 2004 (13.05.2004), abstract, paragraphs 24, 27, 36, 38, 39, 44, and 45, and figure 1.	51, 53-55, and 64
P		
Y	US 5,117,829 A (MILLER et al) 02 June 1992 (02.06.1992), column 3, lines 50-66.	51
Y	PENNEY et al., "A Comparison of Similarity Measures for Use in 2-D--3-D Medical Image Registration", IEEE Transactions on Medical Imaging, August 1998, Vol 17, No. 4, pages 586-595, especially page 592.	8 and 51
A	US 2004/0267113 A1 (THOMSON, EUAN) 30 December 2004 (30.12.2004), abstract and figure 1.	3
A	US 6,470,207 B1 (SIMON et al) 22 October 2002 (22.10.2002), abstract, and column 4, lines 1-12.	1-90

<input type="checkbox"/>	Further documents are listed in the continuation of Box C.	<input type="checkbox"/>	See patent family annex.
*	Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A"	document defining the general state of the art which is not considered to be of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E"	earlier application or patent published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"I,"	document which may throw doubts on priority claims(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&"	document member of the same patent family
"O"	document referring to an oral disclosure, use, exhibition or other means		
"P"	document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search <u>29 April 2005 (29.04.2005)</u>	Date of mailing of the international search report <u>06 SEP 2005</u>
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230	Authorized officer <i>For Michelle R. Curr</i> Chih-Cheng Glen Kao Telephone No. (571) 272-2800

INTERNATIONAL SEARCH REPORTInternational application No.
PCT/US04/27158**BOX III. OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING**

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fees must be paid.

Group I, claim(s) 1-30 and 85-90, drawn to a method, system, and apparatus including adjusting the relative position of a radiation beam generator and a target by an amount prescribed by 3D transformation parameters.

Group II, claim(s) 31-67, drawn to a method and system including determining a set-of in-plane transformation parameters (x, y, θ) and out-of-plane rotational parameters (r, ϕ), said parameters representing the difference in position of a target as shown in an x-ray image as compared to the position of the target as shown by a reconstructed image, wherein r and ϕ represent the rotations of said target about first and second mutually orthogonal axes, said rotations being out-of-plane with respect to an image plane, said out-of-plane rotations representing the projection of said target onto said image plane; and wherein x and y represent the amount of translation of said target within said image plane in the directions of said x - and y -axes, respectively, and θ represents the amount of rotation of said target within said image plane about an axis perpendicular to both said x - and said y -axes.

Group III, claim(s) 68-84, drawn to a method and system including forming a difference image by subtracting pixel values of a second image from pixel values of a first image, and summing asymptotic functions of gradients of said difference image over all the pixels within a neighborhood R , wherein said neighborhood R is defined so that said gradients of said different image can be considered in at least four directions.

The inventions listed as Groups I, II, and III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Regarding Group I, the rest of the Groups lack the same or corresponding adjusting of a relative position of a radiation beam generator and a target by an amount prescribed by 3D transformation parameters.

Regarding Group II, the rest of the Groups lack the same or corresponding determining of a set-of in-plane transformation parameters (x, y, θ) and out-of-plane rotational parameters (r, ϕ), said parameters representing the difference in position of a target as shown in an x-ray image as compared to the position of the target as shown by a reconstructed image, wherein r and ϕ represent the rotations of said target about first and second mutually orthogonal axes, said rotations being out-of-plane with respect to an image plane, said out-of-plane rotations representing the projection of said target onto said image plane; and wherein x and y represent the amount of translation of said target within said image plane in the directions of said x - and y -axes, respectively, and θ represents the amount of rotation of said target within said image plane about an axis perpendicular to both said x - and said y -axes.

Regarding Group III, the rest of the Groups lack the same or corresponding forming of a difference image by subtracting pixel values of a second image from pixel values of a first image, and summing of asymptotic functions of gradients of said difference image over all the pixels within a neighborhood R , wherein said neighborhood R is defined so that said gradients of said different image can be considered in at least four directions.

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:
MARK G. LAPPIN
MCDERMOTT WILL & EMERY LLP
28 STATE STREET
BOSTON, MA 02109

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

		Date of mailing (day/month/year)	06 SEP 2005
Applicant's or agent's file reference		FOR FURTHER ACTION See paragraph 2 below	
63564-104			
International application No.	International filing date (day/month/year)	Priority date (day/month/year)	
PCT/US04/27158	20 August 2004 (20.08.2004)	29 August 2003 (29.08.2003)	
International Patent Classification (IPC) or both national classification and IPC			
IPC(7): A61B 5/05;A61N 5/10 and US Cl.: 378,4,62,63,65,205;382/132;600/427,429			
Applicant			
ACCURAY, INC.			

1. This opinion contains indications relating to the following items:

<input checked="" type="checkbox"/>	Box No. I	Basis of the opinion
<input type="checkbox"/>	Box No. II	Priority
<input type="checkbox"/>	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
<input checked="" type="checkbox"/>	Box No. IV	Lack of unity of invention
<input checked="" type="checkbox"/>	Box No. V	Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
<input type="checkbox"/>	Box No. VI	Certain documents cited
<input type="checkbox"/>	Box No. VII	Certain defects in the international application
<input checked="" type="checkbox"/>	Box No. VIII	Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/ US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230	Authorized officer <i>Chih-Cheng Glen Kao</i> Chih-Cheng Glen Kao Telephone No. (571) 272-2800
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Form PCT/ISA/237 (cover sheet) (January 2004)

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

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Box No. I Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

This opinion has been established on the basis of a translation from the original language into the following language _____, which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).

2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

a sequence listing
 table(s) related to the sequence listing

b. format of material

in written format
 in computer readable form

c. time of filing/furnishing

contained in international application as filed.
 filed together with the international application in computer readable form.
 furnished subsequently to this Authority for the purposes of search.

3. In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

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INTERNATIONAL SEARCHING AUTHORITY

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Box No. IV Lack of unity of invention

1. In response to the invitation (Form PCT/ISA/206) to pay additional fees the applicant has:
 paid additional fees
 paid additional fees under protest
 not paid additional fees
2. This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.
3. This Authority considers that the requirement of unity of invention in accordance with Rule 13.1, 13.2 and 13.3 is:
 complied with
 not complied with for the following reasons:

See the lack of unity section of the International Search Report (Form PCT/ISA/210)

4. Consequently, this opinion has been established in respect of the following parts of the international application:
 all parts.
 the parts relating to claims Nos. _____

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INTERNATIONAL SEARCHING AUTHORITY

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Box No. V Reasoned statement under Rule 43 bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims <u>4-8, 11-21, 23-84, and 86</u>	YES
	Claims <u>1-3, 9, 10, 22, 85, and 87-90</u>	NO
Inventive step (IS)	Claims <u>4-7, 11-21, 23-84, and 86</u>	YES
	Claims <u>1-3, 8-10, 22, 85, and 87-90</u>	NO
Industrial applicability (IA)	Claims <u>1-90</u>	YES
	Claims <u>NONE</u>	NO

2. Citations and explanations:

Please See Continuation Sheet

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

PCT/US04/27158

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the questions whether the claims are fully supported by the description, are made.

Claims 35 and 36 are objected to under PCT Rule 66.2(a)(v) as lacking clarity under PCT Article 6 because the claims are indefinite for the following reason(s):

Claim 36 recites "said 3D matching process". However, there is insufficient antecedent basis for this recitation in the claim. This objection may be obviated by changing the dependency of claim 35 from claim 1 to claim 31.

For purposes of examination, the claims have been treated as such.

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

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Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

V. 2. Citations and Explanations:

1. Claims 1-3, 9, 10, 22, 85, and 87-90 lack novelty under PCT Article 33(2) as being anticipated by Murphy et al. (US Patent 5901199).

Regarding claims 1 and 85, Murphy et al. discloses a method and apparatus comprising a 3D scanner configured to generate a pre-treatment 3D scan showing the position of said target at treatment planning time (column 4, lines 24-30); an image reconstructor configured to generate a set of 2D reconstructed images from said 3D scan (column 4, lines 37-43); an x-ray imaging system for generating in near real time one or more 2D x-ray images of said target, wherein said x-ray images show the position of said target at a current time during treatment (column 4, line 67, to column 5, line 10); an image registration system configured to register said reconstructed images with said x-ray images by computing a set of 3D transformation parameters that represent the change in position of target between said 3D scan and said x-ray images (column 5, lines 11-19); and a position adjuster configured to adjust, in near real time, the relative position of said radiosurgical beam generator and said target by the amount prescribed by said 3D transformation parameters computed in step d (column 5, line 32, to column 6, line 14); wherein said target is allowed six degrees of freedom of position (column 4, lines 57-63).

Regarding claim 2, Murphy et al. further discloses wherein said 3D transformation parameters represent the difference between the position of the target at said treatment planning time, and the position of the target at said current time (column 4, lines 49-56).

Regarding claim 3, Murphy et al. further discloses repeating steps c through e quasi-continuously during treatment, whereby one or more radiosurgical beams generated by said beam generator remain properly focused onto said target throughout said radiosurgical treatment (column 9, lines 18-19).

Regarding claims 9 and 88-90, Murphy et al. further discloses wherein said x-ray images generated in step c comprise x-ray projection images that represent at least two orthogonal projections A and B of said target onto respective projection image planes, said x-ray projection images being formed by transmitting at least two x-ray imaging beams with an x-ray imaging beam generator through said target and onto said respective image planes, wherein each imaging beam is received by a respective x-ray camera after passing through said target (figure 3, #42).

Regarding claim 10, Murphy et al. further discloses generating two sets of reconstructed images, one set for each of said projections A and B (column 5, lines 11-19).

Regarding claims 22 and 87, Murphy et al. further discloses the 3D scan comprising at least one of a CT scan with a CT scanner (column 4, lines 24-26).

2. Claim 8 lacks an inventive step under PCT Article 33(3) as being obvious over Murphy et al. as applied to claim 1 above, and

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Supplemental Box

In case the space in any of the preceding boxes is not sufficient:

further in view of Penney et al. ("A Comparison of Similarity Measures for Use in 2-D-3-D Medical Image Registration"). Murphy et al. discloses a method as recited above.

However, Murphy et al. does not disclose wherein said 3D transformation parameters are 3D rigid body transformation parameters, and wherein said 3D transformation parameters are represented by three translations and three rotations (x, y, z, r, p, w); wherein x, y, z represent the translations of said target in the directions of three mutually orthogonal axes, respectively, and wherein r, p, w represent three rotations (roll, pitch, yaw) about said three orthogonal axes.

Penney et al. teaches wherein said 3D transformation parameters are 3D rigid body transformation parameters, and wherein said 3D transformation parameters are represented by three translations and three rotations (x, y, z, r, p, w); wherein x, y, z represent the translations of said target in the directions of three mutually orthogonal axes, respectively, and wherein r, p, w represent three rotations (roll, pitch, yaw) about said three orthogonal axes (table 1 and page 592, section C).

It would have been obvious, to one having ordinary skill in the art at the time the invention was made, to incorporate the method of Murphy et al. with the parameters of Penney et al., since one would be motivated to make such a modification to reduce computing time (page 592, column 2, paragraph 3) as implied from Penney et al.

3. Claims 4 and 5 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest a method including the step of creating a treatment plane after step a and before step b, in combination with all the limitations in each respective claim.

4. Claim 6 meets the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest a method including the step of processing x-ray images, after step c and before step d, so as to match the orientation, image size, and bit depth of said x-ray images with the orientation, image size, and bit depth of reconstructed 2D images, in combination with all the limitations in the claim.

5. Claim 7 meets the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest a method wherein imaging beams have a known intensity, position, and angle, in combination with all the limitations in the claim.

6. Claims 11-15 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest a method including the steps of individually registering each x-ray projection image A and B with their respective set of reconstructed images, by determining a separate set of transformation parameters for each projection x-ray image, and combining the resulting parameters for each projection to obtain said 3D transformation parameters, in combination with all the limitations in each respective claim.

7. Claims 16-21 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest a method including the steps of individually computing the transformation parameters (x_A, y_A, θ_A) and (x_B, y_B, θ_B) for each projection image A and B; and combining the transformation parameters for projection A with the transformation parameters for projection B so as to obtain said 3D transformation parameters; and wherein said 3D transformation parameters are represented by three translations and three rotations (x, y, z, r, p, w) in combination with all the limitations in each respective claim.

8. Claims 23-30 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest a system including an imaging beam source for generating at least one imaging beam having a known intensity, and having a known position and angle relative to a target, and means for generating at least one reconstructed 2D image, based on 3D scan data, and using said known intensity, location, and angle of said imaging beam, in combination with all the limitations in each respective claim.

9. Claims 31-50 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest a method including the steps of determining the value of in-plane transformation parameters (x, y, θ) and out-of-plane rotational parameters (r, ϕ) for registering a reconstructed image onto an x-ray image, said parameters representing a difference in position of a target as shown in said x-ray image, as compared to the position of the target as shown by said image reconstructed from 3D scan data, obtaining an initial estimate for in-plane transformation parameters (x, y, θ) by multi-level matching in three dimensions, between an x-ray image and a reconstructed image, based on parameters estimated in step a, performing an initial search in one dimension for each of the pair of out-of-plane rotation parameters (r, ϕ), and iteratively refining said in-plane parameters (x, y, θ) and said out-of-plane parameters (r, ϕ) until said in-plane and out-of-plane parameters converge to a desired accuracy, in combination with all the limitations in each respective claim.

10. Claims 51-67 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest a system including a radiation source for generating at least one radiographic imaging beam having a known intensity, and having a known position and angle relative to a target, and means for generating at least one reconstructed 2D image of said target, using 3D scan data, and using said known location, angle, and intensity of said imaging beam, in combination with all the limitations in each respective claim.

11. Claims 68-81 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest a method including the step of forming a pattern intensity function by summing asymptotic functions of gradients of a difference image over all

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Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

the pixels within a neighborhood R, wherein said neighborhood R is defined so that said gradients of said difference image can be considered in at least four directions, in combination with all the limitations in each respective claim.

12. Claims 82-84 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest a system including software adding asymptotic functions of gradients of a difference image over all the pixels within a neighborhood R, wherein said neighborhood R is defined so that said gradients of said difference image can be considered in at least four directions, in combination with all the limitations in each respective claim.

13. Claim 86 meets the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest an apparatus including an x-ray image processor configured to process the near real time x-ray images so that the orientation, image size, and bit depth of x-ray images match the orientation, image size, and bit depth of reconstructed 2D images, in combination with all the limitations in the claim.

14. Claims 1-90 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.

NOTESTOFORMPCT/ISA/220

These Notes are intended to give the basic instructions concerning the filing of amendments under Article 19. The Notes are based on the requirements of the Patent Cooperation Treaty, the Regulations and the Administrative Instructions under that Treaty. In case of discrepancy between these Notes and those requirements, the latter are applicable. For more detailed information, see also the *PCT Applicant's Guide*, a publication of WIPO.

In these Notes, "Article," "Rule" and "Section" refer to the provisions of the PCT, the PCT Regulations and the PCT Administrative Instructions, respectively.

INSTRUCTIONS CONCERNING AMENDMENTS UNDER ARTICLE 19

The applicant has, after having received the international search report, one opportunity to amend the claims of the international application. It should however be emphasized that, since all parts of the international application (claims, description and drawings) may be amended during the international preliminary examination procedure, there is usually no need to file amendments of the claims under Article 19 except where, e.g. the applicant wants the latter to be published for the purposes of provisional protection or has another reason for amending the claims before international publication. Furthermore, it should be emphasized that provisional protection is available in some States only.

What parts of the international application may be amended?

Under Article 19, only the claims may be amended.

During the international phase, the claims may also be amended (or further amended) under Article 34 before the International Preliminary Examining Authority. The description and drawings may only be amended under Article 34 before the International Preliminary Examining Authority.

Upon entry into the national phase, all parts of the international application may be amended under Article 28 or, where applicable, Article 41.

When ? Within 2 months from the date of transmittal of the international search report or 16 months from the priority date, whichever time limit expires later. It should be noted, however, that the amendments will be considered as having been received on time if they are received by the International Bureau after the expiration of the applicable time limit but before the completion of the technical preparations for international publication (Rule 46.1).

Where not to file the amendments?

The amendments may only be filed with the International Bureau and not with the receiving Office or the International Searching Authority (Rule 46.2).

Where a demand for international preliminary examination has been/is filed, see below.

How ? Either by cancelling one or more entire claims, by adding one or more new claims or by amending the text of one or more of the claims as filed.

A replacement sheet must be submitted for each sheet of the claims which, on account of an amendment or amendments, differs from the sheet originally filed.

All the claims appearing on a replacement sheet must be numbered in Arabic numerals. Where a claim is cancelled, no renumbering of the other claims is required. In all cases where claims are renumbered, they must be renumbered consecutively (Administrative Instructions, Section 205(b)).

The amendments must be made in the language in which the international application is to be published.

What documents must/may accompany the amendments?

Letter (Section 205(b)):

The amendments must be submitted with a letter.

The letter will not be published with the international application and the amended claims. It should not be confused with the "Statement under Article 19(1)" (see below, under "Statement under Article 19(1)").

The letter must be in English or French, at the choice of the applicant. However, if the language of the international application is English, the letter must be in English; if the language of the international application is French, the letter must be in French.

NOTES TO FORM PCT/ISA/220 (continued)

The letter must indicate the differences between the claims as filed and the claims as amended. It must, in particular, indicate, in connection with each claim appearing in the international application (it being understood that identical indications concerning several claims may be grouped), whether

- (i) the claim is unchanged;
- (ii) the claim is cancelled;
- (iii) the claim is new;
- (iv) the claim replaces one or more claims as filed;
- (v) the claim is the result of the division of a claim as filed.

The following examples illustrate the manner in which amendments must be explained in the accompanying letter:

- 1 [Where originally there were 48 claims and after amendment of some claims there are 51]:
"Claims 1 to 29, 31, 32, 34, 35, 37 to 48 replaced by amended claims bearing the same numbers;
claims 30, 33 and 36 unchanged; new claims 49 to 51 added."
- 2 [Where originally there were 15 claims and after amendment of all claims there are 11]:
"Claims 1 to 15 replaced by amended claims 1 to 11."
- 3 [Where originally there were 14 claims and the amendments consist in cancelling some claims and in adding new claims]:
"Claims 1 to 6 and 14 unchanged; claims 7 to 13 cancelled; new claims 15, 16 and 17 added." or
"Claims 7 to 13 cancelled; new claims 15, 16 and 17 added; all other claims unchanged."
- 4 [Where various kinds of amendments are made]:
"Claims 1-10 unchanged; claims 11 to 13, 18 and 19 cancelled; claims 14, 15 and 16 replaced by amended claim 14; claim 17 subdivided into amended claims 15, 16 and 17; new claims 20 and 21 added."

"Statement under Article 19(1)" (Rule 46.4)

The amendments may be accompanied by a statement explaining the amendments and indicating any impact that such amendments might have on the description and the drawings (which cannot be amended under Article 19(1)).

The statement will be published with the international application and the amended claims.

It must be in the language in which the international application is to be published.

It must be brief, not exceeding 500 words if in English or if translated into English.

It should not be confused with and does not replace the letter indicating the differences between the claims as filed and as amended. It must be filed on a separate sheet and must be identified as such by a heading, preferably by using the words "Statement under Article 19(1)."

It may not contain any disparaging comments on the international search report or the relevance of citations contained in that report. Reference to citations, relevant to a given claim, contained in the international search report may be made only in connection with an amendment of that claim.

Consequence if a demand for international preliminary examination has already been filed

If, at the time of filing any amendments and any accompanying statement, under Article 19, a demand for international preliminary examination has already been submitted, the applicant must preferably, at the time of filing, the amendments (and any statement) with the International Bureau, also file with the International Preliminary Examining Authority a copy of such amendments (and of any statement) and, where required, a translation of such amendments for the procedure before that Authority (see Rules 55.3(a) and 62.2, first sentence). For further information, see the Notes to the demand form (PCT/IPEA/401).

Consequence with regard to translation of the international application for entry into the national phase

The applicant's attention is drawn to the fact that, upon entry into the national phase, a translation of the claims as amended under Article 19 may have to be furnished to the designated/elected Offices, instead of, or in addition to, the translation of the claims as filed.

For further details on the requirements of each designated/elected Office, see the *PCT Applicant's Guide*, Volume II.